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November 10,1998

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204

## Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

## **Supports a Healthy Urinary Tract**

Provides a special combination of traditional herbs which have historically been used to help maintain urinary tract health and reduce excess body water.

on the following product:

Tree of Life® Herbal Water Tablets

Very truly yours,

Leiner Health Products

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Manager of Regulatory Affairs

975 - 0162

Also see docket 975-0163

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